OCT 8 - 2004

K042410



# 510(k) SUMMARY

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|---|---|
| **Date Prepared** | September 3, 2004 |
| **510(k) Number** | |
| **Submitter** | Baxter Healthcare<br>Baxter BioScience<br>One Baxter Way<br>Westlake Village, CA 91362 |
| **Contact** | Ron Lagerquist<br>Senior Manager, Regulatory Affairs |
| **Device Name** | BAXJECT II Needleless Transfer Device |
| **Common/Usual/ Classification Name** | Set, I.V. Fluid Transfer<br>LHI |
| **Device Description** | BAXJECT II is a dual sided needleless transfer device designed for transferring and mixing drugs contained in two vials into a syringe. The double-sided device has a vial holder on each end. Siliconized plastic piercing spikes are designed for easy penetration into the rubber stopper of standard 20mm vials. A deployable tube reduces the potential for foaming during reconstitution of powdered materials. The device filters air passing into the system to relieve vacuum. A standard luer connector with embedded product filter allows for the mixed drug to be transferred into a syringe. |
| **Intended Use** | The BAXJECT II Needleless Transfer Device is intended for transferring and mixing drugs contained in two vials into a syringe. |
| **Predicate Device** | Needleless Transfer Device<br>MediMop Medical Projects, LTD<br>K001831 |
| **Substantial Equivalence** | The BAXJECT II is substantially equivalent to the predicate device based on technological characteristics and intended use. The BAXJECT II Needleless Transfer Device conforms with the FDA Guidance Document, "Guidance for Industry and FDA Review Staff: Guidance on Premarket Notifications for Intravascular Administration Sets, October 12, 2000" |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

Baxter Healthcare Corporation
C/O Mr. Ronald F. Lagerquist
Senior Manager, Regulatory Affairs
Baxter BioScience
One Baxter Way
Westlake Village, California 91362

Re: K042410
Trade/Device Name: BAXJECT I I
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: September 28, 2004
Received: September 29, 2004

Dear Mr. Lagerquist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

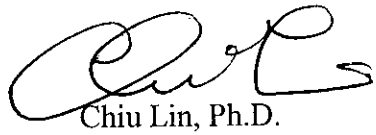
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042410



## Indications for Use

510(k) Number (if known): K042410

Device Name: BAXJECT II

Indications for Use:

The BAXJECT II Needleless Transfer Device is intended for transferring and mixing drugs contained in two vials into a syringe.

Vicki Hubbard for Anthony Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042410

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|---|---|---|---|
| Prescription Use (Part 21 CFR 801 Subpart D) | X | AND/OR | Over-The-Counter Use (21 CFR 807 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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